CERTIFICATE OF MAIL UNDER 37 C.F.R. 1.10

Express Mail Label: EV 182 095 393 US

Date of Deposit: July 15, 2003

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail" addressed to the Mail Stop Patent

Application Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Art Unit: Not yet assigned

DAVID E. SILVERMAN et al.

Examiner: Not yet assigned Application No. Not yet assigned

Herewith Filed:

For: Method for Treating Fecal Incontinence July 15, 2003 Date:

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Applicant submits herewith patents and publications which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. §1.56. While this Statement may be "material" pursuant to 37 C.F.R. §1.56, it is not intended to constitute an admission that any patent, publication, or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Enclosed herewith are PTO/SB/8A & SB/8B forms listing art potentially relevant or of interest to the referenced patent application. This application relies on the earlier filing dates of prior Application Nos. 09/882,522, filed June 15, 2001; 09/286,245, filed April 5, 1999 and 09/232,056 filed January 15, 1999, under 35 U.S.C. § 120. It is understood that the Examiner will consider information that was submitted to or cited by the Office in such prior applications. Notice of April 20, 1992; 1138 OG 37-41, at 37. Copies of documents previously submitted to or cited by the Office in the prior applications are not required to be provided in this application and thus are not attached. 37 C.F.R. § 1.98(d).

This information disclosure statement is being filed in compliance with 37 CFR 1.97(b)(3) as being filed before the mailing date of the first office action on the merits.

Should any questions or comments arise regarding the listing of the submitted publications and patents in which the Examiner feels a telephone conversation would be appropriate, he or she is respectfully requested to contact the undersigned attorney at the listed telephone number.

Respectfully submitted,

DORSEY & WHITNEY LLP

Edward N. Bachano

Reg. No. 37,085

Suite 3400 Four Embarcadero Center San Francisco, CA 94111-4187 Telephone: (650) 494-8700

1060473

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

									Complete if Known							
INFORMATION DISCLOSURE								Application Number				To be assigned				
INFORMATION DISCLOSUI STATEMENT BY APPLICAN								Filing Date		July 15, 2003						
STA	TE	MEN	IT B	BY A	PP	LIC	ANT	First Named Inventor Group Art Unit		DAVI	D E. SILVERMAN	-				
										To be assigned						
								Examiner Name				To be assigned				
Sheet	1			of	3	Attorney			ney Do				013-1/ENB			
	-					U.S. PATENT DOC			JMEN							
Examiner Initials'	Cite No.1					Name	ument Cited Do		of Publication of ed Document		Pages, Columns, Lines, Where Relevant					
÷									j	MM	I-DD-YY	*	Passages or Relevant Figures Appear			
		Number Kind Code ² (if known)														
	Αl	3,0	94,122	2			Gauthier et	al.	06/18/196			3				
	Bl	3,2	04,63	4					09	/07/196	5					
	Cl	4,3	51,33	3			Lazarus et	al.		09	/28/198	2				
	DI	4,4	24,20	8			Wallace et	al.		01/03/1984						
	E1_	4,5	82,64	0			Smestad et	al.		04/15/1986						
	Fl	4,7	73,39	3			Haber et a	ıl.		09/27/1988						
	GI	4,8	03,07	5			Wallace et	al.		02/07/1989						
	Hl		37,28				Berg et a	l		06/06/1989			· · · · · · · · · · · · · · · · · · ·			
	11		07,94			Berg				04/16/1991						
	Jl	5,0	67,96	5		Ersek et al.				11/26/1991						
	K1	5,1	16,38	7		Berg				05/26/1992						
	LI		58,573	$\overline{}$		Berg				10/27/1992						
	M1	5,2	04,382	2		Wallace et al.				04/20/1993						
	NI	5,2	5,258,028			Ersek et a				11/02/199						
	01	5,3	5,301,682			Debbas			04/12/19		/12/199	4				
	P1	ļ														
	Q1				-				\perp							
	R1	ti l		ļ												
	G:	I = :-	Š			FO	REIGN PATE					1.10	T D	Т°		
Examiner Initials'	Cite Foreign Patent Document No. 1						entee or Applicant ted Document			Date of Publication of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant				
		Office ³	Nun	nber ⁴	Kind C (if kno											
	S1	wo	98/1			\vdash	PCT			04/30/19						
	TI	wo	98/1					PCT		04/30						
	Ul	wo		98/01088				PCT		01/15/1						
	V1	wo	97/45131				PCT			12/04/1997						
	WI	wo	97/19643			\sqcup		PCT		06/05/						
	XI	AU	A-34223/95			 		AU		05/02/		1996	ļ			
}	Υl															
	Zl															
Examiner	Т	L	L						Date	 •						
Signature										sidere	d					
	\top		-			<u>. </u>					+					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MFEF 609. Draw line inrough citation in not in conformance with MFEF 609. Draw line inrough citation in not in conformance with MFEF 609. Draw line inrough citation in more incompleted communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 3 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if

possible. Applicant is to place a check mark here if English Language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

							Complete if Known						
TAITS	OD:	N #F A #TE	ION D	100	T O	מו מו דר	Application	n Number		assigned			
			ION D				Filing Dat		July 15, 2003				
STA	TE	MEN	T BY	API	PLIC	CANT	First Named Inventor		DAVID E. SILVERMAN				
							Group Art Unit			assigned			
							Examiner		To be assigned				
Sheet	2		of	3				Oocket Number		0013-1/ENB			
Silect				1,		J.S. PATENT	•		A-700	713-176110			
Examiner	Cite	U.S. Pat	ent Documen	t T		of Patentee or		Date of Publicat	ion of	Pages, Columns, Lines,			
Initials'	No.'					of Cited Doc		Cited Docum MM-DD-YY	ent	Where Relevant Passages or Relevant Figures Appear			
		1	r Kind Cod nown)	e²									
	A2	5,336,263				Ersek et a	ıl. 08/09/		4				
	B2	5,451,406				Lawin et a	al.	09/19/199	5				
	C2	5,480,644				Freed		01/02/199	6		-		
	D2	5,490,984				Freed	02/13/1996		6				
	E2	5,580,568			*	Greff et a	l.	12/03/199	6				
	F2	5,667,767				Greff et a	1.	09/16/199					
	G2	5,695,480		\Box		Evans et a	ıl.	12/09/199	7	• • • •			
	H2	5,702,361				Evans et a	ıl.	12/30/1997					
	12	5,755,658				Wallace et	al.	05/26/199	8				
	J2	5,785,642			Wallace et al.			07/28/199					
,	K2	5,792,478			Lawin et al.			08/11/199					
	L2	5,830,178				Jones et a		11/03/199					
	M2	6,251,063			Silverman et al.			06/26/200			-		
	N2	6,251,064				Silverman e		06/26/200					
	O2	2001/0018548				Silverman e	et al. 08/30/200						
	P2												
	Q2								-				
	R2												
	L	<u>l</u> .		LL	FC	REIGN PATE	NT DOCUM	I IENTS			-		
Examiner Initials'	Cite No.1	Foreign I	Patent Docum	ent			entee or Appli ted Document		•	Pages, Columns, Lines, Where Relevant Passages or Relevant	Te		
		007.3			d Code ²								
	S2	Office ³	Number ⁴	(if kı	nown)								
	T2				 								
	U2				-					<u> </u>			
	V2				+					1			
	W2				-								
	X2				+								
	Y2												
	Z2								_				
Examiner Signature							Dan Con	te nsidered					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Unique citation designation number. See attached Kinds of U.S. Patent Documents. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English Language Translation is attached.

**Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

Please type a plus sign (+) inside this box → 🗹 + U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

					Complete if Known								
INE)DM	ATION	DΙ	SCLOSURE	Applic	ation Number		To be assigned					
					Filing Date			July 15, 2003					
STA				APPLICANT	First N	amed Inventor		DAVID E. SILVERMAN					
	(use a	as many sheets	as	necessary)	Group	Art Unit		To be assigned					
					Exami	ner Name		To be assigned					
Sheet	3	of	f	3	Attorne	y Docket Numb	oer	A-70013-1/ENB					
	1			OR ART - NON PATE									
Examiner Initials'	Cite No. ¹	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.											
	A3	Donahue, P. et al., "Endoscopic Sclerosis Of The Gastric Cardia For Prevention Of Experimental Gastroesophageal Reflux" (1990) Gastrointestinal Endoscopy, pp. 253-256.											
	В3	Klingman, R.R. et al., "The Current Management of Gastroesophageal Reflux", (1991), Adv. Surg., Vol. 24, pp. 259-291.											
	С3	Malizia, A. et al., "Migration and Granulomatous Reaction After Periurethral injection of Polytef (Teflon)", (June 1984), JAMA, Vol. 251, No. 24, pp. 3277-3281.											
	D3	O'Connor, K.W. et al., "Endoscopic placement of collagen at the lower esophageal sphincter to inhibit gastroesophageal reflux: a pilot study of 10 medically intractable patients", (1988), Gastrointestinal Endoscopy, Vol. 34, No. 2, pp. 106-112.											
	E3	O'Connor, K. W. et al., "An experimental endoscopic technique for reversing gastroesophageal reflux in dogs by injecting inert material in the distal esophagus", (1984) Gatrointestinal Endoscopy, Vol. 30, No. 5, pp. 275-280.											
	F3	Ortiz, A. et al., "Conservative treatment versus antireflux surgery in Barrett's oesophagus: long-term results of a prospective study", (1996), <i>Brit. Jnl. of Surg.</i> , Vol. 83, 274-278.											
	G3	Politano, V.A., et al., "Periurethral Teflon Injection for Urinary Incontinence", (February 1974) <i>Jnl. Urology</i> , Vol. 111, pp. 180-183.											
	НЗ	Schulman, C.C. et al., "Endoscopic injections of Teflon to treat urinary incontinence in women", (January 21, 1984) <i>BMJ</i> , Vol. 228, p. 192.											
	13	Shafik, A., "Intraesophageal Polytef injection for the treatment of reflux esophagitis", (1996), Surgical Endoscopy, pp. 329-331.											
	J3	Walker, R.D. et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene", (August 1992), J. Urol., Vol. 148, pp. 645-647.											
	K3												
	L3												
	M3												
	N3												
	O3												
Examiner Signature						Date Considered		<u> </u>					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include

copy of this form with next communication to applicant.

Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.